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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,792	06/13/2001	Yonghong Xiao	02973.00035	3733

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EXAMINER

RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/02/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,792

Applicant(s)

XIAO ET AL.

Examiner

Delia M. Ramirez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-73 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-15, 22-24, 27, 62-64, 69-71, drawn to DNA, vectors, host cells encoding and expression of the polynucleotide of SEQ ID NO: 11, classified in class 536, subclass 23.2.
 - II. Claims 16-21, drawn to the polypeptide of SEQ ID NO: 12, classified in class 435, subclass 219.
 - III. Claims 30, 56-58, 61, 72, drawn in part to an antibody against the polypeptide of SEQ ID NO: 12 and compositions comprising said antibody, classified in class 530, subclass 387.1.
 - IV. Claims 58-59, drawn in part to a composition comprising a ribozyme, classified in class 435, subclass 91.31.
 - V. Claims 58, 60, 73, drawn to an antisense oligonucleotide which hybridizes to the polynucleotide of SEQ ID NO: 11 and compositions comprising said oligonucleotide, classified in class 536, subclass 23.1.
 - VI. Claims 25-26, drawn to a method of detecting a coding sequence, classified in class 436, subclass 94.
 - VII. Claims 28-29, drawn to a method of detecting a polypeptide comprising the amino acid sequence of SEQ ID NO: 12, classified in class 436, subclass 501.

- VIII. Claims 31-39, drawn to a method of screening for agents which bind a human transmembrane serine protease comprising the polypeptide of SEQ ID NO: 12, classified in class 436, subclass 501.
- IX. Claims 40-47, drawn to a method of screening therapeutic compounds which can regulate the activity of a human transmembrane serine protease comprising the polypeptide of SEQ ID NO: 12, classified in class 436, subclass 86.
- X. Claims 48-55, drawn to a method of reducing the activity of a human transmembrane serine protease comprising the polypeptide of SEQ ID NO: 12, classified in class 436, subclass 512.
- XI. Claims 65-68, drawn to a method of treating a disorder using an inhibitor of the activity of a human transmembrane protein comprising the polypeptide of SEQ ID NO: 12, classified in class 424, subclass 130.1.

The inventions are distinct, each from the other because of the following reasons:

2. Groups I, II, III, IV, and V each comprise a chemically unrelated structure capable of separate manufacture, use, and effect. The DNA in Group I, the ribozyme of Group IV and the antisense oligonucleotide of Group V each comprise a nucleic acid sequence whereas the proteins of Group II, III, and IV each comprise an unrelated amino acid sequence. Neither the DNA of Group I, the antisense oligonucleotide of Group V, nor the ribozyme of Group IV are required one for the other and are used in materially different and distinct processes. The DNA of Group I has other uses besides encoding the protein of Group II, such as a hybridization probe. The antisense oligonucleotide has other uses besides that of a hybridization probe, such as in gene therapy or a composition of its own. The ribozyme of Group IV can be used as a

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hybridization probe or as a therapeutic composition. The protein from Group II can be used in materially different methods other than to make the antibody of Group III, such as in therapeutic or diagnostic methods (e.g. in screening). Further, the proteins of Group II and III can be prepared by processes which are materially different from recombinant DNA expression of Group I, such as by chemical synthesis, or by isolation and purification from natural sources.

3. Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA of Invention I can be used to make the polypeptide of Invention II as well as in the method of Invention VI.

4. Inventions II and VIII or IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II can be used in the methods of Inventions VIII or IX.

5. Inventions III and VII, X, or XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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§ 806.05(h)). In the instant case the antibody of Group III can be used in the methods of Inventions VII, X or XI.

6. Inventions IV and X, or XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the ribozyme of Invention IV can be used in the methods of Inventions X or XI.

7. Inventions V and X or XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antisense oligonucleotide of Invention V can be used in the methods of Inventions X or XI.

8. Inventions VI and VII, VIII, IX, X, or XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods of Inventions VI, VII, VIII, IX, X or XI are not disclosed as capable of use together, comprise different steps, utilize different products, and produce different results.

9. Because these inventions are distinct for the reasons given above, the search is not co-extensive, and have acquired a separate status in the art because of their recognized divergent

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subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.


13. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288.

The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


NASHAAT T. NASHED PHD.
PRIMARY EXAMINER

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
June 28, 2002